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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/707,990

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Borje Sellergren

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21186

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02/20/2009

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EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/707,990	Applicant(s) SELLERGREN ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 11, 2008 has been entered.

Response to Arguments/Amendments

Applicant's arguments and amendments filed November 11, 2008 with the RCE (and previously on 9/11/08) are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Election/Restrictions

Claims 7-9 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 7, 2005 and July 6, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by MOSBACH (US Patent 6,489,418 B1).

The instant claims are drawn to synthesis of a molecularly-imprinted material (MIM), also known in the art as molecularly-imprinted polymers (MIP), comprising the steps of binding

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the peptide to a surface modified support, polymerizing monomers, e.g. acrylamides and/or methacrylates, using heat, UV, or a crosslinking agent, e.g. AIBN, and removing the support/peptide (dissolve/degrade) to generate the free MIM.

Applicant has amended the claim to recite that the peptide corresponds "to an epitope of a target peptide or protein." (step (a), claim 1), specifically a dipeptide or oligopeptide (claim 2). Applicant argues that Mosbach does not disclose the use of a peptide epitope of a target protein/peptide. Respectfully, as indicated in the previous Office Actions, Applicant has admitted that all peptides are equivalent and obvious variants over each other- specifically in the response to the restriction (6/6/05) stating, "Responsive to the election requirement for a single peptide as among those set forth in claims 2, 4, and 9, Applicants do not maintain that these variants are patentably distinct." (emphasis added; page 5, 2nd paragraph, 6/6/05; and repeated in reply of 7/6/05). Further, Applicant has not defined in the specification what constitutes an 'epitope' of a target protein/peptide, and thus in the broadest reasonable interpretation can include the entire protein. Claim 2 is a generic claim and in looking to the specification, Applicant exemplifies nociceptin as an oligopeptide (e.g. ¶ [0032]). Thus, the interpretation that the epitope can be a complete peptide is consistent with Applicant's disclosure. Accordingly, Applicant's amendments do not further distinguish from the prior art.

Mosbach teaches a general synthesis of a MIM in Example 3 (column 5) where trypsin is immobilized on agarose beds, and monomers are polymerized with a crosslinker and the agarose beads are dissolved with addition of an acidic solution.

In Example 4 (column 5), Mosbach further teaches attachment of insulin to a surface-modified silica surface, which has been modified to have N-hydroxysuccinimide esters as

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pendant groups. As discussed in previous Office Actions, attachment of insulin to the silica is equivalent to 'synthesis', given that Applicant's specification includes attachment of an amino acid to the surface as 'synthesis'. Imprinting is conducted with either a methacrylate/ styrene/ acrylamide/ bisacrylamide solution with the photoinitiator being methylene blue, or with VBIDA, MAA and EGDMA with AIBN as the initiator. The imprint is "a stable film which can be separated from the surface on which it has been formed, e.g. manually or by dissolution." (column 5, lines 65-67). Figure 6 provides a complementary scheme of the synthesis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over MOSBACH, as applied to claims 1-3, 5 and 6, *supra*.

The instant claims are presented *supra*, and are further drawn to various peptides useable in the method. Applicant argues that the amendments overcome the anticipation rejection, as discussed above, and therefore it is not obvious. Applicant further argues that "Applicant did not admit that the peptides, support, or monomers are not patentably distinct. Rather, Applicant

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stated that with regards to the peptide, monomers, and support, while those compounds/compositions may be patentably distinct as compounds/compositions, within the context of the method claims, it is not necessary to argue about their actual composition at this time..." (Remarks, page 7). Respectfully, Applicant's original response(s) does/did not make this newly presented statement as to what the allegedly was being argued with regards to obvious variants, and the statement saying they are not patentably distinct was made twice- once on June 6, 2005 and then reiterated on July 6, 2005. Thus, the rejection is maintained for the reasons of record.

Mosbach teaches the method for is usable for enzymes, antigens, and antibodies (e.g. claim 17).

Because Applicant has admitted on the record that there is no patentable distinction between the peptide epitope of claim 2 and the species recited in claim 4, it would have been obvious to have used any peptide, including those recited, in practicing the method. Additionally, because Applicant has admitted that the method is patentable "irrespective of the support used" and "irrespective of the [monomer] mixture used", , it would have been obvious to have used any monomer mixture and any support, including those recited, in practicing the method. One would have been motivated to use any peptide, as Applicant has stated that there is no patentable distinction, and because Mosbach teaches you can use any peptide. One would have been motivated to use any support and monomer mixture, as Applicant has stated that there is no patentable distinction, and because Mosbach teaches using monomers and supports One would have a reasonable expectation for success in practicing the method, as MIP synthesis is

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widely practiced in the art, and Applicant states that the method can be practiced with any peptide, support and monomer mixture because they are not patentably distinct from one another.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654